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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,743	08/31/2000	Mads Norregaard-Madsen	5665.400-US	3499

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/652,743

Applicant(s)

NORREGAARD-MADSEN ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 48-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-58 is/are allowed.
- 6) ☒ Claim(s) 59-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

*Response to Amendment*

Applicant's Amendment C, Paper No. 14 filed December 3, 2002 has been entered. Applicant's argument at page 7 of Paper No. 14 is persuasive and the objection of record to the specification is withdrawn. Claims 1, 20, 32-34 and 40-47 were canceled at Applicant's request, rendering rejections of record of these claims for lack of an adequate written description and lack of enablement under the first paragraph of 35 U.S.C. § 112 moot. The new claims 48-84 submitted with Paper No. 14 were added and these new claims avoid the rejections of record of claims herein under 35 U.S.C. § 102(a) and under 35 U.S.C. § 112, first paragraph. Claims 48-58 are allowed herewith. It is acknowledged that Applicant's new claims 59-84 comport with the suggestion made at page 13, lines 8-14 of Paper No. 11 mailed July 3, 2002, but a close inspection of SEQ ID NO:12 by comparison with the recitations of claims 59, 65, 70, 73, 76 and 77 indicate that the disclosures at pages 23-32 of the specification are in part, erroneous, with regard to many of the proposed modifications of SEQ ID NO:12. Thus amended claims 59-84 require the following, new grounds of rejection under the second paragraph of 35 U.S.C. § 112.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is indefinite because it recites, in clause (d), "any amino acid susceptible to oxidation", but the specification describes but a single amino acid that is susceptible to oxidation, methionine, thus the scope of the claim is ambiguous where the public, seeking to interpret the claim, cannot determine what might have been intended by its scope. Claim 59 is also indefinite because it recites, in clause (e), "any Trp at the surface [of the

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residual protease of SEQ ID NO:12]", but the amino acid sequence shown in SEQ ID NO:12 has no tryptophan present anywhere among the 302 amino acids of the preprotease, whether in the signal peptide, the propeptide, or the mature protease, let alone at position 142 of the mature protease, which is lysine, thus the scope of the claim is ambiguous where the public, seeking to interpret the claim, cannot determine what might have been intended by its scope. Claims 60-84 are included in this rejection of claim 59 because they depend therefrom but do not independently resolve the ambiguities of clauses (d) and (e) therein and amending clause (d) of the claim to delete "amino acid" and to insert "methionine" instead, as well as deleting clause (e) will overcome this aspect of the rejection.

Claim 65 is independently indefinite because it describes amino acid substitutions in SEQ ID NO:12 recited as E143A, E151A and E202A, as well as the substitutions in SEQ ID NO:12 recited as D96A, D103A, D152A, D161A and D173A. There are no glutamates at positions 143, 151 or 202 in the mature protease of SEQ ID NO:12, nor are there any aspartates at positions 96, 103, 152, 161 and 173 in the mature protease of SEQ ID NO:12. Instead, glutamates occur at positions 81 – properly indicated in the claim – and at positions 147, 155, and 207, while aspartates occur 5, 6, 69, 135 – all properly indicated in the claim – and at positions 156, 165 and 177. Deletion of the erroneously recited positions from claim 65 will overcome this aspect of the rejection.

Claim 70 is independently indefinite because it describes amino acid substitutions of serine, alanine, asparagine, glutamine, or lysine, for a methionine at either of positions 144 or 171 in SEQ ID NO:12 or a deletion of a methionine at either of positions 144 or 171 in SEQ ID NO:12. There are no methionines at positions 144 or 171 in the mature protease of SEQ ID NO:12. Instead, methionines occur at positions 67, 79, and 137 –

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all properly indicated in the claim – and at positions 148 and 175. Deletion of the erroneously recited positions from claim 70 will overcome this aspect of the rejection.

Claim 73 is independently indefinite because it describes amino acid substitutions of phenylalanine, glycine, glutamine, or threonine, for a tryptophan at position 142 in the mature protease of SEQ ID NO:12. But tryptophan is not present anywhere in the amino acid sequence of SEQ ID NO:12, thus deletion of claim 73 will overcome this aspect of the rejection.

Claims 76 and 77 are independently indefinite because they describes amino acid substitutions in SEQ ID NO:12 for tyrosines occurring at positions recited as 95, 112, 157, 158, 186 and 306 in the mature protease of SEQ ID NO:12 whereby claim 77 further describes phenylalanine or tryptophan substituents at these seven positions. There are no tyrosines at positions 95, 112, 157, 158, 186 and 206 in the mature protease of SEQ ID NO:12. Instead, tyrosines at occur at positions 19, 24, 50, 57, 64, 83, 88, and 132 – all properly indicated in the claim – and at positions 96, 113, 161, 162, 190 and 211. Deletion of the erroneously recited positions from claims 76 and 77 will overcome this aspect of the rejection.

*Allowable Subject Matter*

Claims 48-84 are free of the prior art for the reasons set forth at pages 12 and 13 of Paper No. 11.

*Conclusion*


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. The examiner's direct FAX telephone number is 703.746.3169. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

15 William W. Moore  
February 24, 2003

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISOR, EXAMINER  
FEB 24 2003